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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,021	02/06/2004	Orn Adalsteinsson	ARK-153US1	7718

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McCarter & English LLP
Citizens Bank Center
919 N. Market Street, Suite 1800
P.O. Box 111
Wilmington, DE 19899

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,021	ADALSTEINSSON ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-59* is/are pending in the application.

4a) Of the above claim(s) *52-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *46-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 46-51 are under examination. Claims 52-59 are withdrawn from consideration because they are drawn to non-elected inventions.

Specification

2. The objection to the specification, page 1, because the status of parent application, USSN 09/656,712, was not been updated to reflect that USSN 09/656,712 is now US Patent 6,706,267. is withdrawn in view of Applicant's amendment to the specification.

3. (*New Objection*) The amendment filed February 15, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: International Publication Number WO 00/43020. While Applicant asserts that WO 00/43020 is the PCT counterpart to the deleted reference, USSN 09/233,379, there is statement in the original filing of the instant application that the PCT was to be incorporated by reference. Applicant is required to cancel the new matter in the reply to this Office Action.

Oath/Declaration

4. The objection to the oath or declaration for being defective is withdrawn in view of the declaration filed with the response on February 15, 2006.

Claim Objections

5. The objection to claim 49 for reciting, "HCI" instead of "HCl" is withdrawn in view of Applicant's amendment to claim 49.

Claim Rejections - 35 USC § 112

6. The rejection of claims 46 and 48-51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained. The rejection of claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of Applicant's amendment that corrects the improper Markush group.

The claims remain rejected, however, because of the indefiniteness of the term "active" egg fraction. Also undefined is "partially purified anti-inflammatory fraction of the egg", which is from the yolk. What component is the active fraction or the anti-inflammatory fraction? The examples show a whole egg, yet the "active" fraction and "anti-inflammatory fraction" is not identified. Is Applicant referring to IgY? The metes and bounds of the "active" egg fraction cannot be determined without a definition.

Applicant's arguments regarding "active egg fraction" have been carefully considered but fail to persuade. Applicant's substantive argument is primarily directed to the argument that the claims, as amended, indicate that the active egg fraction comprises "supranormal levels of an anti-inflammatory composition".

In response to Applicant's argument, the new limitation does not define the active egg fraction. The new limitation is a further component of the egg fraction, but does not define what

the egg fraction is. The new limitation itself has indefiniteness because "supranormal levels of an anti-inflammatory composition" is not defined in the specification. The term, "supranormal" is a relative term that lacks comparative basis. One cannot know the metes and bounds of the claims without an understanding of what constitutes a supranormal level of an anti-inflammatory composition. Further, it appears that Applicant is attempting to improperly incorporate a definition into the specification, and thus the claims, from International Publication Number WO 00/43020. This incorporation by reference is not proper, and thus WO 00/43020 cannot be relied upon to define any terms in the instant specification and claims. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

7. Claim 46 remains rejected under 35 U.S.C. 102(b) as being anticipated by Kondo *et al.* (US 4,367,309, "Kondo"), for reasons of record. Claim 46 is drawn to a composition comprising glucosamine and an active egg fraction, wherein the active egg fraction further comprises supranormal levels of an anti-inflammatory composition. (The specification does not clearly define "active" egg fraction, nor "supranormal levels of an anti-inflammatory composition", so the egg fraction is interpreted as any egg fraction with no specific activity required.) Kondo discloses a composition comprising a glycoprotein (conjugated protein) containing a carbohydrate. Specifically, the glycoprotein is egg albumin and the carbohydrate is glucosamine (column 2, lines 5-22). Therefore, lacking a clear definition of "active egg fraction", the claim remains anticipated by Kondo.

Applicant's argument has been considered, but fails to persuade. Applicant argues that Kondo fails to teach an active egg fraction that further comprises supranormal levels of an anti-inflammatory composition. In response to Applicant's argument, the definitions of the "active" egg fraction, and "supranormal levels of an anti-inflammatory composition" are not clearly or appropriately defined (improper incorporation by reference). Therefore, the claim remains rejected for reasons of record.

Claim Rejections - 35 USC § 103

8. The rejection of claims 46-51 under 35 U.S.C. 103(a) as being unpatentable over Adalsteinsson *et al.* (WO 99/36077, "Adalsteinsson") in view of Yue (US 6,251,863), is maintained for reasons of record. The claims are drawn to a composition comprising glucosamine and an active egg fraction, wherein the active egg fraction further comprises supranormal levels of an anti-inflammatory composition. (The specification does not clearly define "active" egg fraction, nor "supranormal levels of an anti-inflammatory composition", so the egg fraction is interpreted as any egg fraction with no specific activity required.) The egg fraction is egg yolk, or a partially purified anti-inflammatory fraction of the yolk. (The specification does not clearly define "anti-inflammatory fraction of the yolk", so the anti-inflammatory fraction is interpreted as any egg fraction of a yolk with anti-inflammatory activity.) The glucosamine is glucosamine HCl or glucosamine sulfate, in the amount of approximately 10 mg to 5 grams. The immunogenic vaccine that is used to hyperimmunize the chicken from which the egg is taken, comprises various immunogens selected from a list in claim 51.

Adalsteinsson teaches a composition comprising an egg or fraction thereof, wherein the egg has been hyperimmunized with at least one antigen (abstract). The antigen is from bacteria, viruses, protozoa, fungi and cellular antigens (Adalsteinsson, claim 8). The composition also contains NSAIDs or DMARDs (claim 23). Adalsteinsson fails to teach glucosamine as part of the composition.

However, Yue teaches that glucosamine sulfate has been shown to treat joint disease. Yue suggests that it is a preferable treatment for the inflammation and pain of the joints instead of NSAIDS (col. 5, lines 19-26). It would have been obvious to substitute the glucosamine sulfate of Yue for Adalsteinsson's NSAIDs or DMARDs. One would have been motivated by Yue's teaching that glucosamine sulfate is a preferable treatment for inflammation instead of NSAIDs. One of ordinary skill in the art would have had a reasonable expectation of success that glucosamine would work in Adalsteinsson's method because Adalsteinsson uses an anti-inflammatory drug, and glucosamine is a known anti-inflammatory treatment, evidenced by Yue. Determining the dosages of glucosamine and egg would have been well within the ability of one of ordinary skill. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time of the invention.

Applicant's arguments have been fully considered but fail to persuade. Applicant argues that there would be no need in Yue for the use for the hyperimmune egg of Adalsteinsson as there is no need to protect the gastrointestinal tract from damage from glucosamine. Applicant asserts that Adalsteinsson specifically teaches the use of the hyperimmune egg to protect the gastrointestinal tract from damage resulting from NSAIDs or DMARDs. Applicant argues that NSAIDs and DMARDs are well known in the art to cause severe gastrointestinal damage,

especially when taken in high doses. Applicant argues that here is no such effect/damage caused by glucosamine, thus there is no motivation for one to turn to Adalsteinsson for use of the hyperimmune egg together with Yue's disclosure of glucosamine.

In response to Applicant's arguments, the obviousness analysis is based on the substitution of glucosamine sulfate (taught by Yue) for the NSAIDs or DMARDs in Adalsteinsson's composition. Yue teaches that glucosamine sulfate has been shown to treat joint disease. Yue suggests that it is a preferable treatment for the inflammation and pain of the joints instead of NSAIDS (col. 5, lines 19-26). It would have been obvious to substitute the glucosamine sulfate of Yue for Adalsteinsson's NSAIDs or DMARDs. One would have been motivated by Yue's teaching that glucosamine sulfate is a preferable treatment for inflammation instead of NSAIDs.

Applicant has not addressed why the Office's analysis of the motivation to combine the references cannot stand. Applicant has presented their own combination of references and reasons therefore, however, the merits of the rejection have not been argued. Therefore, the claims remain rejected for reasons of record.

Double Patenting

9. The rejection of claims 46-51 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,706,267 B1, is maintained for reasons of record. Applicant indicates that a terminal disclaimer may be filed once allowable subject matter is indicated.

Conclusion

10. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen 4/11/06

Stacy B. Chen
Primary Examiner
April 11, 2006